IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

Biomedical Device Consultants & Laboratories of Colorado, LLC Plaintiff, v. TA Instruments – Waters LLC, Defendants.	Civil No. 0:17-cv-03403 DWF-SER

OPPOSITION BY TA INSTRUMENTS
TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I. INTRODUCTION

In seeking a preliminary injunction, BDC faces an uphill battle. BDC must demonstrate *every* one of the following: (1) a likelihood of substantial and immediate harm that cannot be compensated with money; (2) a substantial likelihood that it will succeed on infringement; (3) a substantial likelihood that it will succeed on validity; and (4) a substantial likelihood that it will succeed on enforceability. If BDC fails to demonstrate even *one* of these elements, it cannot obtain a preliminary injunction. Here, BDC does not meet a single one of these requirements.

BDC's own conduct demonstrates that even BDC does not believe the alleged harm is urgent enough to warrant the extraordinary measure of a preliminary injunction. BDC waited years even to file suit, and then waited almost another four months after that to seek a preliminary injunction. Nothing in BDC's conduct or its briefing merits entry of a preliminary injunction.

II. APPLICABLE LAW

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.,* 555 U.S. 7, 22 (2008). "[A] plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Titan Tire Corp. v. Case New Holland, Inc*., 566 F.3d 1372, 1375 (Fed. Cir. 2009) (quoting *Winter*, 555 U.S. at

20).[1] To obtain a preliminary injunction, a plaintiff must establish (1) a likelihood of success as to infringement, validity, *and* enforceability, *and* (2) irreparable harm. *See Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996) ("The movant [for a preliminary injunction] bears the burden of proving entitlement to relief.").

A. Irreparable Harm

"Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes *both* ... likelihood of success on the merits and irreparable harm." *Polyform A.G.P., Inc. v. Xtreme Insulation Techs., LLC*, No. 17-735, 2017 WL 4564719, at *5 (D. Minn. Oct. 11, 2017) (emphasis in original) (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001)).

"As the party seeking injunctive relief, [the plaintiff] must make a 'clear showing' that it is at risk of irreparable harm." *Rudolph Techs., Inc. v. Camtek Ltd.*, No. 15-1246, 2015 WL 5039295, at *14 (D. Minn. Aug. 26, 2015) (quoting *Winter*, 555 U.S. at 22). To meet this burden, the plaintiff must establish "a likelihood of substantial and immediate irreparable injury." *Apple, Inc. v. Samsung Elec. Co., Ltd.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

There is no presumption of irreparable harm. *See, e.g.*, *3M Co. v. Avery Dennison Corp.*, No. 10-2630, 2010 WL 5288168, at *9 (D. Minn. Dec. 21, 2010) ("Courts no longer presume irreparable harm from a mere showing that a patentee is likely to succeed

[1] "[A] preliminary injunction involves substantive matters unique to patent law, and therefore governed by [Federal Circuit] law." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988).

on the merits. Instead, the Court must look at the factual record and assess this prong independently.") (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006)).

B. Likelihood of Success on the Merits

The patent holder has the burden of showing likelihood of success on the merits on all three issues: infringement, validity, and enforceability. *See, e.g.*, *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2012). If the party seeking the preliminary injunction cannot show likelihood of success on any of infringement, validity, *and* enforceability, it cannot succeed. *See, e.g.*, *Novo Nordisk of North America, Inc. v. Genentech, Inc*., 77 F.3d 1364, 1371 (Fed. Cir. 1996).

If the party opposing the motion for preliminary injunction "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." *Amazon.com*, 239 F.3d at 1350-51.

The presumption of patent validity "does not relieve a patentee who moves for a preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity." *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1351 (Fed. Cir. 2000). "If the alleged infringer raises a substantial question concerning validity, *i.e.*, asserts an invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue." *Id.*

Moreover, if a patentee fails to present a proper claim construction position to show infringement, a patentee cannot meet its burden of proving likelihood of success. *See, e.g.*, *Fair Isaac Corp. v. Int'l Bus. Machines Corp*., No. 05-2081, 2006 WL 1283852, *7 (D. Minn. May 9, 2006) (Frank, J.) ("The Court finds that in light of the incomplete claim construction and infringement analysis provided to the Court, Fair Isaac has not met its burden of demonstrating a likelihood of success on the merits of its patent infringement claim.").

C. Balance of Harms

The balance of harms factor "assesses the relative effect of granting or denying an injunction on the parties." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010).

D. Public Interest

"Typically, in a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech*, 849 F.2d at 1458. "[W]here the patent holder has not established a likelihood of success on the merits, the public interest weighs against granting an injunction." *Polyform*, 2017 WL 4564719, at *6 (citing *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006)).

III. ARGUMENT

A. BDC Has Failed to Demonstrate Any Irreparable Harm

BDC fails to show any actual damage and, even if there were harm, fails to show that money could not compensate BDC. Specifically, BDC argues that its alleged irreparable harm is (1) lost market share, (2) "threaten[ed]" price erosion, (3) lost revenue that would, theoretically, have been used for R&D, and (4) injury to reputation. Dkt. 36, BDC's Memorandum of Law in Support of its Motion for Preliminary Injunction ("BPI") at 22-26. Courts "look … to evidence of what actual damage was likely due to any continuation of [the accused infringer]'s alleged infringing sales and whether money damages will provide adequate compensation and vindication of [the patentee]'s patent rights." *See Reebok Intern. Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1557 (Fed. Cir. 1994) (affirming denial of preliminary injunction). A claim of irreparable harm that is, like BDC's, based merely on speculation cannot succeed. *See, e.g., Nutrition 21 v. U.S.*, 930 F.2d 867, 871 (Fed. Cir. 1991) ("Neither the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial.").

As explained below, BDC fails to establish harm, and also fails to show that any alleged harm would not be compensable by monetary damages.

1. BDC Offers No Admissible Evidence Regarding Irreparable Harm

BDC offers no admissible evidence supporting its claim of irreparable harm. The sum total of BDC's alleged "evidence" of irreparable harm is (1) unsupported double

hearsay statements of an unknown, unnamed "customer," (2) vague and unsubstantiated claims about BDC's share of an undefined market; and (3) speculation and attorney argument.

First, BDC relies on a declaration by its CEO, Dr. Weinberg, relaying what he was allegedly told by an unnamed "customer." BPI at 11; Dkt. 39, Declaration of Craig Weinberg ("Weinberg Decl.") ¶ 22. In other words, BDC relies on double hearsay to "prove" that a customer chose TA Instruments over BDC and (allegedly) did so based in part on price. *See id.* This is not sufficient to support a preliminary injunction. *See, e.g.*, *U.S. Water Servs., Inc. v. Watertech of Am., Inc.*, No. 13-1258, 2013 WL 5503725, at *3 (D. Minn. Oct. 3, 2013) (denying motion for preliminary injunction and holding that statement allegedly by unidentified employee reported in CEO's affidavit was inadmissible hearsay); *Watkins Inc. v. Lewis*, No. 02-3708, 2002 WL 31319491, at *15 (D. Minn. Oct. 11, 2002), *aff'd*, 346 F.3d 841 (8th Cir. 2003) (hearsay evidence from unidentified persons was insufficient to show likelihood of success); *A & L Labs., Inc. v. Bou-Matic, LLC*, No. 02-4862, 2003 WL 21729977, at *4 (D. Minn. July 21, 2003) (denying motion for preliminary injunction and disregarding inadmissible portions of affidavit prepared in support of the motion). BDC has no way of identifying the alleged "customer," let alone corroborating Dr. Weinberg's account of the supposed conversation or determining what other reasons influenced the alleged sale.[2]

[2] While some courts may consider hearsay evidence in ruling on motion for a preliminary injunction, they do so "if the evidence is 'appropriate given the character and objectives of the injunctive proceeding.'" *Levi Strauss & Co. v. Sunrise Intern. Trading Inc.*, 51 F.3d 982, 985 (11th Cir. 1995). Here, BDC chose not to offer the declaration of any

Second, the only information that BDC offers regarding its "lost market share" is a single, vague, unsupported statement from Dr. Weinberg that BDC enjoys "80-90% of the worldwide market." Weinberg Decl. ¶11; BPI at 22. What is the relevance of the "worldwide market"? How does it compare to the U.S. market? BDC never explains. In any event, BDC never identifies any loss in its share of any market, "worldwide" or otherwise. In other words, even taking Dr. Weinberg's unsupported claim of an "80-90% share" on face value, BDC never ties it to any alleged irreparable harm.

Finally, BDC's remaining argument on irreparable harm constitutes pure speculation and attorney argument, without any factual support. *See, e.g.*, BPI at 27 ("unless TA Instruments' infringement is enjoined, BDC *will likely* have to lower its prices.") (emphasis added). Other than the alleged loss of one sale—evidenced only by the inadmissible double-hearsay claims regarding the alleged decision of a single unidentified customer—BDC alleges no actual loss or harm of any kind. "A preliminary injunction will not issue simply to prevent a mere possibility of injury, even where prospective injury is great. A presently existing actual threat must be shown." *Zenith Radio Corp. v. US.,* 710 F.2d 806, 809 (Fed. Cir. 1983). Here, BDC fails to offer any credible evidence in support of irreparable harm.

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alleged "customer." Instead, the *only* evidence supporting any alleged harm that BDC offers is Dr. Weinberg's unsupported description of a statement allegedly made by an unknown person. This double-hearsay is not appropriate, particularly as evidence on which to grant a preliminary injunction.

2. BDC Fails to Establish Lost Market Share

Even if BDC *had* offered some evidence of lost sales—which it has not—such evidence would still be insufficient. "Lost sales alone cannot establish irreparable injury." *3M*, 2010 WL 5288168, at *11 (citing *Reebok*, 32 F.3d at 1558); *see also Automated Merch. Sys., Inc. v. Crane Co.*, 357 Fed. Appx. 297, 300-01 (Fed. Cir. 2009) ("lost sales standing alone are insufficient to prove irreparable harm; if they were, irreparable harm would be found in every case involving a 'manufacturer/patentee, regardless of circumstances'").

BDC argues that it is likely to lose sales because "[c]ustomers will generally purchase a single testing system and run a short pilot program." BPI at 8 (citing Weinberg Decl. ¶11). Dr. Weinberg offers nothing to support this assertion and, in any event, TA Instruments disputes it. The products in the market are very expensive, frequently costing more than $100,000 per device. Declaration of Troy Nickel ("Nickel Decl.") at ¶ 6. Customers in this market demand access to the systems before purchasing, and are able to test out the devices before making any purchasing decision. *Id.* at ¶ 7. For example, TA Instruments allows potential customers to test its systems, whether at TA Instrument's laboratory or at the customer's facility. *Id.* at ¶ 8. Moreover, TA Instruments actually loans systems to potential customers for up to several months before deciding whether to purchase. *Id.* at ¶ 9. In other words, customers in this market make informed decisions about what to buy *before* purchasing these expensive systems. *Id.* at ¶ 7.

Moreover, BDC's vague reference to a "worldwide market for heart valve

durability testing systems," even defined narrowly, still underrepresents the competition. Dr. Weinberg claims that "there are only four competitors in the market": BDC, TA Instruments, Dynatek and ViVitro. Weinberg Decl. ¶ 10; BPI at 7. However, as Mr. Nickel explains, Dr. Weinberg failed to disclose at least competitor, Blockwise. Nickel Decl. ¶ 5. And as Mr. Nickel explains, BDC has at most 60% of the market in which TA Instruments and BDC compete, and that only if that "market" is defined narrowly. *Id.* at ¶ 5. BDC's self-serving choice of which competitors to include in its "market" cannot support a claim of irreparable harm. For example, in *Cordance Corp v. Amazon.com, Inc.*, like here, the patent owner tried to define the market too narrowly, excluding most competitors, a definition the court rejected. 730 F. Supp. 2d 333, 340 (D. Del. 2010).

Finally, BDC offers no evidence whatsoever that it has lost its share of *any* market, merely conjecturing "it is only a matter of time before TA Instruments captures a significant piece of the market." BPI at 22. This is pure speculation. It is also attorney argument, not evidence, and therefore cannot satisfy BDC's burden. "Bare pleadings and attorney argument ... are not evidence and do not satisfy the plaintiff's burden." *Interface, Inc. v. J & J Industries, Inc.*, No. 4:13-47, 2013 WL 5945336, *2 (N.D. Ga. 2013). *See also Polyform,* 2017 WL 4564719, at *5 (denying preliminary injunction where patent owner "provides no evidence regarding the current state of the ICF market or evidence that it has lost market share … [and] does not provide evidence of price erosion.").

3. BDC Fails to Establish Price Erosion

BDC's price erosion argument is based entirely on speculation. Specifically, BDC assumes that TA Instruments must have lowered its price because it (TA Instruments)

allegedly got a single sale from an unnamed customer. BPI at 22. BDC offers no evidence whatsoever of what price TA Instruments offered or is offering, other than the list price, which is *higher* than BDC's list price. *See id.* BDC does not allege that it has lowered its own prices or (other the one alleged "sale" to an unnamed customer) that it has lost any sales due to price. As explained above, mere attorney argument and speculation cannot support a preliminary injunction. *See supra* Section III.A. Moreover, even if BDC had produced evidence in support of price erosion—which it is has not—"[e]vidence of price erosion and loss of market share does not, in and of itself, demonstrate irreparable harm." *3M*, 2010 WL 5288168, at *11.

4. BDC's Unsupported Claim of Loss of Research Funds Is Insufficient

BDC contends that its alleged irreparable harm includes "loss of [R&D] funds[]." BPI at 24-25. But if loss of funds, alone, could constitute irreparable harm, "[s]uch a rule would convert the 'extraordinary' relief of a preliminary injunction into a standard remedy…" *Eli Lilly and Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996). In *Eli Lilly*, like here, the patentee argued that its lost profits would result in irreparable harm to the patentee's overall research efforts. *Id.* at 1578. The Federal Circuit rejected this argument, holding:

> If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a R&D program that could not make the same claim and thus be equally entitled to preliminary injunctive relief. Such a rule would convert the "extraordinary" relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits. For that reason, adopting the principle that Lilly proposes would "disserve the patent system."

Id. *See also Minnesota Mining & Manufacturing v. Alphapharm Pty. Ltd.*, No. 99-13, 2002 WL 1299996 at *5 (D. Minn. March 8, 2002) (in light of *Lilly*, rejecting patentee's argument that lost research opportunities constitute irreparable harm).[3]

5. BDC Shows No Injury to Reputation

Similarly, BDC failed to establish any injury to reputation whatsoever. *See* BPI at 25-26. Instead, BDC cites alleged customer "testimonials" praising BDC, but offers no evidence whatsoever suggesting that BDC has *lost* any reputation, or that it is in danger of doing so. *See id.* Again, mere speculation is not sufficient to support preliminary injunction. *See, e.g., Nutrition 21*, 930 F.2d at 871.

6. Any Harm, if it Existed, Would Be Compensable with Monetary Damages

Even if there were any damages in this case—which there are not—such damages would be easily quantifiable, and a preliminary injunction is inappropriate for that reason alone. *See, e.g.*, *Sampson v. Murray,* 415 U.S. 61, 90 (1974) ("The possibility that adequate compensatory or other corrective relief will be available at a later date . . . weighs heavily against a claim of irreparable harm.") (quoting *Virginia Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958)). In *3M Co. v. Avery Dennison Corp.,* for example, the Court held that the patentee's alleged damages

[3] BDC's cited cases are easily distinguishable. For example, unlike here, the patentee in *Mylan Institutional LLC v. Aurobindo Pharma Ltd.,* No. 216-00491, showed that at least half of its revenue derived from its patented product, that it would need to delay or eliminate its R&D program absent injunction, and that other loan obligations prevented making up the shortfall. *See* 2016 WL 7587325, at *23 (E.D. Tex. Nov. 21, 2016), *aff'd as modified* 857 F.3d 858 (Fed. Cir. 2017). BDC has not even alleged any such circumstances here.

could be compensated by money because, like here, the patentee had been selling its own product for several years and "therefore there is a record of pricing and sales to assist in computing money damages. Any damage as a result of delay or disruption is easily quantifiable." No. 10-2630, 2010 WL 5288168, at *11 (D. Minn. Dec. 21, 2010). BDC's records of pricing and sales of its own product would assist in calculating alleged damages.

7. BDC's Inexcusable, Several Year-Delay in Seeking a Preliminary Injunction Belies Its Claims of Irreparable Harm

BDC's conduct shows that its concerns about alleged infringement are anything but urgent. BDC knew about the alleged infringement as early as 2013. BPI at 10. BDC formally asserted infringement by letter in July 2014. *Id.* BDC sued TA Instruments in July 2017. Dkt. 1. But BDC did not file its motion for a preliminary injunction until November 22, 2017. Dkt. 36.

In other words, BDC waited *four years* after learning of the allegedly infringing product, *three years* after formally asserting infringement, and *nearly four months* after filing the complaint to seek a preliminary injunction.[4] BDC allowed this alleged infringement to continue for years, indicating that any alleged harm is hardly "irreparable." *See, e.g.*, *High Tech Medical Instrumentation, Inc. v. New Image Industries, Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (recognizing delay in seeking

[4] BDC claims it delayed from "December 2015" to November 2017. *See* BPI at 27. Apparently, BDC contends that its delay only began after the accused product was sold to TA Instruments. *See id.* But BDC acknowledges that it was aware of the accused product since 2013, and that it sent a letter alleging infringement in July 2014. *Id.* at 10. BDC's delay runs from before December 2015.

preliminary injunction as an important factor and stating "Absent a good explanation, … 17 months is a substantial period of delay that militates against the issuance of a preliminary injunction by demonstrating that there is no apparent urgency …."); *Nutrition 21*, 930 F.2d at 872 (vacating injunction, finding that patentee "delayed for a substantial period of time before seeking a preliminary injunction [which] at least suggests that the *status quo* does not irreparably damage" the patentee); *Tiber Laboratories, LLC v. Hawthorn Pharmaceuticals, Inc.*, 527 F. Supp. 2d 1373 (N.D. Ga. 2007) ("[T]he Court concludes that the 13-month and 17-month delay in bringing its two infringement actions combined with Tiber's apparent willingness to license the '689 patent preclude a finding of irreparable harm.").[5]

There is no excuse for BDC's delay. BDC claims that it delayed because (1) it did not initially see the allegedly infringing product as a "threat," and (2) because it was negotiating with TA Instruments. BPI at 28. Neither reason excuses the delay. First, BDC claims that it did not seek a preliminary injunction back in 2013 or 2014—when it learned of the accused product and when it formally asserted that the product infringed, respectively—because the product was not a threat until TA Instruments allegedly increased marketing efforts.[6] *Id.* But this is no justification for delay. If BDC truly believed that the alleged infringement could cause irreparable harm, it would have sought

[5] BDC relies on information that could only have been derived from settlement negotiations, which is improper under FRE 408. *See* BPI at 30. It is particularly unfair of BDC to do so while withholding more relevant settlement information.

[6] TA Instruments did *not* "dramatically increase[] marketing efforts" after acquiring the line from Bose. *See* Nickel Decl. ¶ 12.

a preliminary injunction when it realized the product was (allegedly) infringing its patents. *See, e.g.*, *PTT, LLC v. Gimme Games*, No. 13-7161, 2014 WL 5343304, at *3 (D.N.J. Oct. 20, 2014) (finding delay not excused where injunction was sought after new online advertising efforts).

Second, negotiating with the alleged infringer is not an excuse. For example, in *Novozymes A/S v. Danisco A/S,* the court rejected that argument, finding no irreparable harm based on a *two-month* delay:

> Plaintiffs say they waited because they were busy testing defendants' products, getting an expert, preparing their motion and giving defendants 'an opportunity to withdraw [their] infringing products from the market.' However, plaintiffs could have accomplished the first three things in the days leading up to the filing of the lawsuit and they could have negotiated with defendants before *and* after they filed a preliminary injunction motion.

No. 10-251, 2010 WL 3783682, *4 (W.D. Wis. 2010) (emphasis in original). Similarly, in Y*amashita v. Wilbur-Ellis Co.*, the court noted that a three-year delay in filing suit "is at least a persuasive consideration regardless of the purported justifications" and rejected the plaintiff's proffered excuses, including that the parties were negotiating during the delay. No. 06-1690, 2006 WL 1320470, *7 (N.D. Cal. 2006) ("[I]t seems that plaintiffs' supposed negotiations with Wilbur-Ellis took the form of repeated demands to cease and desist. That is not the type of negotiation apt to bear fruit worth delaying litigation for three years.") In any event, BDC does not cite a case for the proposition that a desire to avoid spending money on litigation, alone, is an "excuse" for substantial delay in moving for a preliminary injunction, let alone a several-year delay.

Finally, the nearly four-month delay between filing the complaint and moving for a preliminary injunctions is unjustified. *See, e.g.*, *Precision Links Inc. v. USA Products Group, Inc*., 2009 WL 3076114, *8 (W.D. N.C. 2009) (finding that Plaintiff's delay of "over five months after filing its Complaint … is simply unjustified and demonstrates a lack of any irreparable harm.").

B. BDC Has Failed to Demonstrate a Likelihood of Success on the Merits

To obtain a preliminary injunction, BDC must show that it is likely to succeed on *each* of (1) validity, (2) infringement, and (3) enforceability. BDC has failed to meet this burden on even one of these issues.

First, the public record establishes that Dr. Weinberg (an inventor) mischaracterized and withheld highly material information in his possession to gain allowance of the two patents BDC asserts in its motion. While he claims to have been aware of the state of the art, Dr. Weinberg mischaracterized the art to gain allowance of the two patents. Due to inequitable conduct, BDC should not be allowed to enforce the asserted patents.

Next, even if it were allowed to enforce its patents, BDC failed to demonstrate a likelihood that it will succeed on the merits of its infringement allegations. BDC has already told the Court and the Patent Office that terms in the asserted independent claims are terms of art. But in its motion, BDC proposed a construction of only one term in one asserted dependent claim, even though BDC's own expert apparently believes that construction of the independent claims is necessary. In other words, BDC failed to construe the claims as required to establish infringement.

Finally, even applying BDC's expert's interpretation of the claim terms, the asserted patent claims are invalid over the prior art of record. Contrary to the suggestion of BDC's expert, the '935 patent claims are not infringed. Moreover, the '224 patent is invalid because the '224 application included no written description of the claimed invention. In short, BDC's motion fails on the merits.

1. The Asserted Patents Are Unenforceable Because BDC Withheld and Mischaracterized Highly Material Information.

BDC intentionally withheld and mischaracterized highly relevant information during prosecution, which constitutes inequitable conduct. "The substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009).

The International Standard on "Cardiovascular Implants — Cardiac Valve Prosthesis," ISO 5840, is highly material to the asserted patents. Dr. Weinberg, an inventor and BDC's President and CEO, served on a subcommittee that revised ISO 5840 during the prosecution of the asserted patents. *Compare* Weinberg Decl. ¶¶ 1-2 *with* Ex. 7[7] at Forward (ISO 5840) (both identifying the responsible subcommittee as ISO/TC 150/SC 2). During prosecution of the asserted patents, BDC repeatedly recognized the materiality of ISO 5840. BDC relied on its characterization of ISO 5840:

[7] All references to numbered exhibits (Exhibits 1 through 12) refer to exhibits to the Declaration of Kristen Billiar (filed herewith).

(a) to ascribe definite meaning to claim terms (*see* Ex. 3 at 14-18 (June 17, 2015 Response relying on ISO 5840 as to the meaning of "accelerated," "compliance," and "excess volume area"));

(b) to support new claim limitations (*see id.* at 10, 14-15 (relying on ISO 5840 as support for adding the claim limitation of a "rate of greater than 200 beats per minute")); and

(c) to overcome claim rejections over prior art (*see id.* at 14-18; Ex. A[8] at 10 (Examiner Interview April 29, 2013 [Agenda]); *id.* at 18-19 (May 10, 2013 Response)).

The Patent Office was persuaded by BDC's characterization of ISO 5840. *See* Ex. A at 30 (May 3, 2013 Applicant-Initiated Interview Summary); *id.* at 11 (July 17, 2013 Notice of Allowability); Ex. 3 at 7-8 (Sept. 17, 2015 Notice of Allowability citing BDC arguments based on its characterization of ISO 5840). While including two small excerpts, BDC otherwise failed to provide relevant portions of ISO 5840 to the Patent Office. Thus, BDC purposefully withheld highly material information to gain allowance of asserted patents.

Moreover, BDC's characterization of undisclosed portions of ISO 5840 are either generally misleading or simply untrue. ISO 5840, as a whole, does not support BDC's arguments. For example, Dr. Weinberg suggested that "excess volume area" is a term of art based on ISO 5840. *See id.* at 17 (June 17, 2015 Response); *see also id.* at 7 (September 17, 2015 Notice of Allowability concluding "excess volume area … is a term of art"). But TA Instruments found no use of the claim term "excess volume area" in ISO 5840.

[8] All references to lettered exhibits (Exhibits A through C) refer to exhibits to the Declaration of Kia Freeman (filed herewith).

BDC argued that ISO 5840 "real-time test[ing] … [should include] pressures … that approximate physiological conditions"—unlike ISO 5840 accelerated durability testing. *Id.* at 17 (June 17, 2015 Response). But an ISO 5840 paragraph on durability testing—*which BDC failed to disclose*—provided that "[t]est valves shall experience the full range of occluder *motion associated with normotensive conditions (see Table 1) during testing*." Ex. 7 at §7.2.4.2 (emphasis added). Thus, contrary to BDC's suggestion, ISO 5840 required the use of normal physiological blood pressures and pressure differentials in accelerated durability testing. Intent to deceive may be inferred when the applicant drew attention to less relevant portions of a reference and ignored material portions. *See, e.g.*, *eSpeed, Inc. v. BrokerTec USA, L.L.C.,* 480 F.3d 1129, 1137 (Fed. Cir. 2007) (affirming district court's inference of deceptive intent where declaration "disingenuously states" the reference lacked the relevant teaching); *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.,* 204 F.3d 1368, 1377 (Fed. Cir. 2000) (affirming inequitable conduct finding where applicant "deliberately deceived the examiner into thinking that the [] reference was less relevant that it really was").

Similarly, BDC argued that, although ISO 5840 required the use of a compliance chamber in real-time testing, the use of a compliance chamber / excess volume in accelerated durability testing was "entirely new." *See* Ex. 3 at 17 (June 17, 2015 Response). But ISO 5840 expressly stated that, in the protocols for wear/durability, "valves should be tested in the low compliance chamber." Ex. 7 at §§ F.3.2, F.1. Thus, contrary to BDC's argument, ISO 5840 indicated that the use of a compliance chamber in accelerated durability testing is *not* new.

In fact, years before the alleged invention, the use of compliance chambers in accelerated heart valve test systems was known. At least four prior commercial systems for accelerated testing of heart valve prosthetics featured "adjustable … compliance." Ex. B at 186 (Lu). Dr. Weinberg should have been aware of the commercial use of compliance chamber in accelerated heart valve test systems because he admitted to being "aware of" prior art devices. *See* Ex. A at 19 (May 10, 2013 Response). Indeed, the inclusion of "an adjustable compliance chamber … for additional control of loading forces" in a system for accelerated testing of heart valve prosthetics was known at least as early as 1998. Ex. 12 at 153 (Reul). Thus, BDC misrepresented the state of the art to gain allowance of its asserted patents.

2. BDC's Infringement Claims Fail as a Matter of Law

Every infringement analysis—including as part of a preliminary injunction decision—requires two steps: (1) determining the meaning and scope of the asserted claims through claim construction and (2) comparing the properly construed claims to the accused device. *See, e.g.*, *Unique Functional Prod., Inc. v. Mastercraft Boat Co*., 82 F. App'x 683, 686-87 (Fed. Cir. 2003). A movant's failure to properly construe the claims, alone, is fatal to a motion for preliminary injunction. *See, e.g.*, *Fair Isaac*, 2006 WL 1283852, *7 ("[I]n light of the incomplete claim construction and infringement analysis provided to the Court, [movant] has not met its burden of demonstrating a likelihood of success on the merits of its patent infringement claim.").

Except for a single term (that only appears in one asserted dependent claims), BDC tells the Court that "[n]o construction is necessary" because the meaning of those

terms to a person of skill in the art is "readily apparent even to lay judges." *Id.* at 14. But then BDC goes on to characterize other claim terms. As explained below, BDC tells the Court the claim terms need not be construed, and then interprets the terms—albeit without any of the support or analysis required for proper claim construction. In other words, BDC asks the Court to skip the regular claim construction process altogether for most of the claim terms, and simply take BDC's word that the claims mean whatever BDC says when it reads them onto the accused product. This the Court cannot do. *See, e.g.*, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 996 n.7 (Fed. Cir. 1995) (Mayer, J. concurring) ("A claim must be construed … before deciding infringement") *aff'd*, 517 U.S. 37 (1996).

BDC did not propose construction of any of the following claim terms:

- "configured to drive a test system fluid cyclically … above a normal physiological rate" ('935 patent, claim 1);
- "driving a test system fluid cyclically above a normal physiological rate" ('224 patent, claim 1);
- "system driving stroke that opens the valved prosthetic device" ('224 patent, claim 1);
- "return stroke that closes the valved prosthetic device" ('224 patent, claim 1); and
- "excess volume area" ('935 patent, claim 1 & '224 patent, claim 1).

But, by way of example, it is hardly "readily apparent" that the term "cyclically" means what BDC told the Court that it means. In the December hearing, BDC explained that "a pure sinusoidal waveform … would be *cyclical*, [whereas] an asymmetric wave … is *acyclical*." Ex. C at 39 (December 1, 2017 Mot. Hearing Tr.) (emphasis added). In

other words, BDC indicated that, by including the word "cyclically," the asserted claims require the use of a particular waveform. Nonetheless, in its motion for a preliminary injunction, BDC fails to address the alleged waveform requirement at all.

Another example is the claim term "test system fluid." The declaration of BDC's expert, Mr. Girard, raises questions as to the meaning of even this seemingly simple term. First, Mr. Girard generally explains that "[t]esting systems use a test fluid to mimic blood," and that, in the asserted patents, "the test fluid … approximates blood." Dkt. 41, Declaration of Michael Gerard ("Gerard Decl."), ¶¶ 8, 14. Mr. Girard also distinguishes the "test system fluid" of the asserted patents from "air or another gas." *See id.* at ¶ 20 ("air or another gas … may directly contact the fluid or may be separated from the fluid by a membrane"). He uses a red circle to "depict the fluid line." *Id.* at p. 11. Mr. Girard thereby raises the questions as to whether the "test system fluid" excludes gas and is limited to a liquid that mimics blood. Rather than assisting the Court in determining the meaning and scope of the asserted claims through claim construction, BDC simply raises questions.

Although the term "excess volume area" may seem straightforward, BDC convinced the Patent Office that it is a term of art. *See* Ex. 3 at 7 (September 17, 2015 Notice of Allowability finding that "excess volume area … is a term of art" based on BDC's remarks). In doing so, BDC relied on ISO 5840. *See* Ex. 3 at 17 (June 17, 2015 Response). But the two short excerpts of ISO 5840 that BDC provided to the Patent Office do not use the term "excess volume area." *See id.* at 16-17. BDC never explains what this alleged term of art means.

Finally, BDC argues that the asserted patents "revolutionized the market for heart valve durability testing … with an excess volume area known as a compliance chamber on the outflow side of the valve" (BPI at 7), but fails to explain how the claims require this particular location of the excess volume area. BDC simply asks the Court to accept that argument—without explanation.

And even with respect to the one term for which BDC offers a proposed construction—"[t]he only claim term that arguably is in need of construction is 'compliance chamber'" (BPI at 14)—the proposed construction is mysteriously selected from one part of one sentence in a relevant paragraph. BDC fails to explain why its proposed construction includes only the first part of that sentence. *See* Ex. 6 at 8:59-64 ('538 patent stating "As used herein, 'compliance' refers to the ability of the cavities forming the compliance chambers 135 to absorb some of the pressure placed upon the fluid in the test chamber 106 *and further to control recoil toward the original volume dimensions upon removal of the compressive force*.") (emphasis added); *see also* BPI at 14 (citing the quoted sentence in its claim construction argument). BDC also fails to explain why the construction it used to overcome prior art rejections is not the construction it now proposes. *See* Ex. 3 at 14 (Dr. Weinberg distinguishing the compliance in the Pickard system, in June 17, 2015 Response, by asserting the claimed feature "prevent[s] or minimize[s] the kinetic energy of fluid flow generated by the system driver from translating into high static fluid pressure in the test system during the accelerated frequency testing."). And BDC's proposed construction of "compliance" significantly differs from the definition recommended by the standard it frequently cited

during prosecution. *See* Ex. 7 at § F.2.2 (ISO 5840); *see also* Ex. 3 at 17 (June 17, 2015 Response stating that Annex F of ISO 5840 provides "detailed guidelines for complaint chambers.").

BDC's failure to properly construe the claims, alone, is fatal to its likelihood of success argument. *See, e.g.*, *Fair Isaac*, 2006 WL 1283852 at *7; *see, e.g.*, *Millipore Corp. v. W.L. Gore & Assoc., Inc.*, No. 11-1453, 2011 WL 5513193 (D.N.J. Nov. 9, 2011), *9 (no likelihood of success where movant failed to offer proposed constructions and "the parties' submissions … failed to provide the Court with sufficient detail relating to their claim construction positions.").

3. BDC Failed to Establish That the DuraPulse HVT Instrument Infringes the '935 Patent

To succeed, BDC must establish a likelihood that the accused product satisfies each and every limitation of at least one asserted claim. *See* BPI at 12-13. BDC fails.

a. *The DuraPulse HVT Instrument "Pressure Source" Identified by BDC Does Not Satisfy the "Fluid Communication" Requirement of the '935 Patent.*

The claims of the '935 patent requires "a fluid distribution chamber … in fluid communication with the pressure source." BPI at 15 (element [C]). BDC does not establish a likelihood that the accused product satisfies that limitation.

BDC identifies one part of the accused product as a fluid distribution chamber and another part of the accused product as the pressure source. In particular, BDC and its expert use an arrow to label part of the DuraPulse HVT Instrument as "[C] fluid distribution chamber." BPI at 16; Girard Decl. p. 9. BDC and its expert also assert that

"[B] Drive motor … is a pressure source." *Id.* BDC offers no construction of "fluid communication." And BDC fails to even assert that the portion of the DuraPulse HVT Instrument identified as the fluid distribution chamber is in fluid communication with the drive motor. Indeed, applying BDC's interpretation, there is no "fluid communication" with the drive motor.

Mr. Girard provides an interpretation of "in fluid communication with" in his discussion of a different element of the same claim. Mr. Girard asserts that because "test fluid is able to move from the fluid return chamber to the excess volume area …, the two are 'in fluid communication.'" Girard Decl. at p. 13. In other words, Mr. Girard interprets "fluid communication with" a part to mean that test fluid is able to flow to the part. BDC adopted this interpretation. *See* BPI at 15-19. But applying Mr. Girard's interpretation, there is no fluid communication with the identified pressure source: that is, there is no fluid communication with the DuraPulse HVT Instrument drive motor.

In fact, the DuraPulse HVT Instrument includes a special part just to prevent test fluid from flowing to its drive motor. *See* Nickel Decl. ¶ 10. A picture of the drip guard appears below:

See id. The drip guard serves to prevent test fluid in the DuraPulse HVT Instrument from reaching its drive motor. *See id.* In short, the DuraPulse HVT Instrument does not

infringe the '935 patent at least because there is no fluid communication with its drive motor, which BDC identifies as the claimed "pressure source."

b. *Use of the DuraPulse HVT Instrument Does Not Involve "Test System Fluid … Compression" as Required By the '935 Patent.*

The claims of the '935 patent all require "test system fluid … compression." BPI at 15 (element [F]). In operation, the DuraPulse HVT Instrument uses either "deionized (DI) water or a phosphate buffered saline (PBS) solution" as its test fluid. Nickel Decl. ¶ 11. DI water and PBS solution are both incompressible liquids. *See* Billiar Decl. ¶ 37. According to Professor Billiar, one of skill in the art would understand that there is no compression of an incompressible fluid. *See id.* at ¶ 75. It cannot be compressed. Because its test fluid is incompressible, operation of the DuraPulse HVT Instrument necessarily does not involve test fluid compression. *See id.* at ¶ 75. In short, the DuraPulse HVT Instrument does not infringe the '935 patent at least because there is no "compression" of its incompressible test fluid, as required by the claims.

4. The Asserted Claims of the '935 Patent Are Invalid Over Prior Art

BDC added two substantive limitations to the '935 patent claims to gain allowance. First, apparently hoping to leverage the September 2015 allowance of the '224 patent based on the limitation of its test system operation to "an accelerated pulsed rate of greater than 200 beats per minute," BDC added a similar limitation to the '935 application. In October 2015, BDC limited its claimed device to one having "a pressure source configured to drive a test system fluid cyclically within the device ... at an

accelerated pulsed rate of greater than 200 beats per minute."[9] Ex. 5 at 14 (Oct. 15, 2015 Preliminary Amendment).

BDC hoped to convince that Patent Office that limitation was enough to allow the '935 patent claims. In an Interview with the Patent Office shortly thereafter, Dr. Weinberg spoke "technically to the[] issues." Ex. 5 at 2 (Dec. 9, 2015 Comments describing the Oct. 29, 2015 Interview). Dr. Weinberg "discussed differences between accelerated and non-accelerated prosthetic device testers." Ex. 5 at 12 (Nov. 12, 2015 Examiner-Initiated Interview Summary). But Dr. Weinberg also "discussed the limits of non-accelerated compliance chambers as they relate to the claimed excess volume area." *Id.* at 12.

The Patent Office did not agree that the excess volume area in the test device, as it was then claimed, was distinct from the "non-accelerated compliance chambers," as Dr. Weinberg suggested. Accordingly, the Patent Office proposed to amend the claims to recite what Dr. Weinberg suggested was a difference between known compliance chambers and the claimed excess volume area. Ex. 5 at 9-10 (Nov. 12, 2015 Notice of Allowability including an amendment the Patent Office proposed in the Interview). BDC agreed to amend the claims to require that the excess volume area be "capable of operating at the accelerated pulsed rate." *Id.* at 9-10.

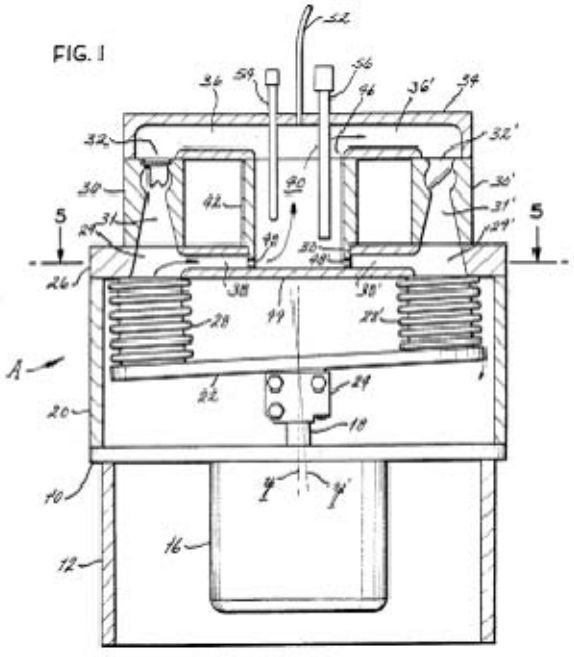
Based on BDC's limitation of both the claimed test device, as a whole, and its excess volume area, as a subcomponent, to operation at "an accelerated pulsed rate of greater than 200 beats per minute," the Patent Office allowed the '935 patent. *See* Ex. 5

[9] At the time, the '935 application did not disclose any particular number of beats per minute.

at 9-10 (Nov. 12, 2015 Notice of Allowability). The Patent Office concluded that "the best prior art of record Pickard et al. (US 4,682,491) and Swanson et al. (US 4,546,642) fail to specifically teach the invention as claimed." *Id.* at 10. The Patent Office explained that "[t]he specific limitation of an accelerated cyclic testing device with an excess volume area capable of operating at the accelerated pulsed rate of greater than 200 beats per minute … distinguish the present invention from the combined prior art." *Id.*

During prosecution of the '935 application, BDC failed to identify any disclosure that would lead one of skill in the art to understand that the excess volume area in Pickard or in Swanson would not be capable of operating at greater than 200 beats per minute. *See* Billiar Decl. ¶ 63. Indeed, Professor Billiar found no disclosure in Pickard or in Swanson that would lead one of skill in the art to understand that the excess volume area in Pickard or the excess volume area in Swanson would not be capable of operating at greater than 200 beats per minute. *See id.*

In fact, U.S. Patent No. 4,546,642 to Swanson ("Swanson") discloses the device of the '935 patent claims 1 and 9. *See* Billiar Decl. ¶¶ 59-81. Swanson discloses a device for accelerated cyclic testing of a valved prosthetic device. *See* Billiar Decl. ¶¶ 64-65 (citing Swanson). Swanson's System A is a device for accelerated cyclic testing of prosthetic heart valves. *See id.* at ¶ 65. Swanson illustrates System A in Figures 1 through 5. *See id.*. For reference, Figure 1 of Swanson is copied below.



Swanson Fig. 1

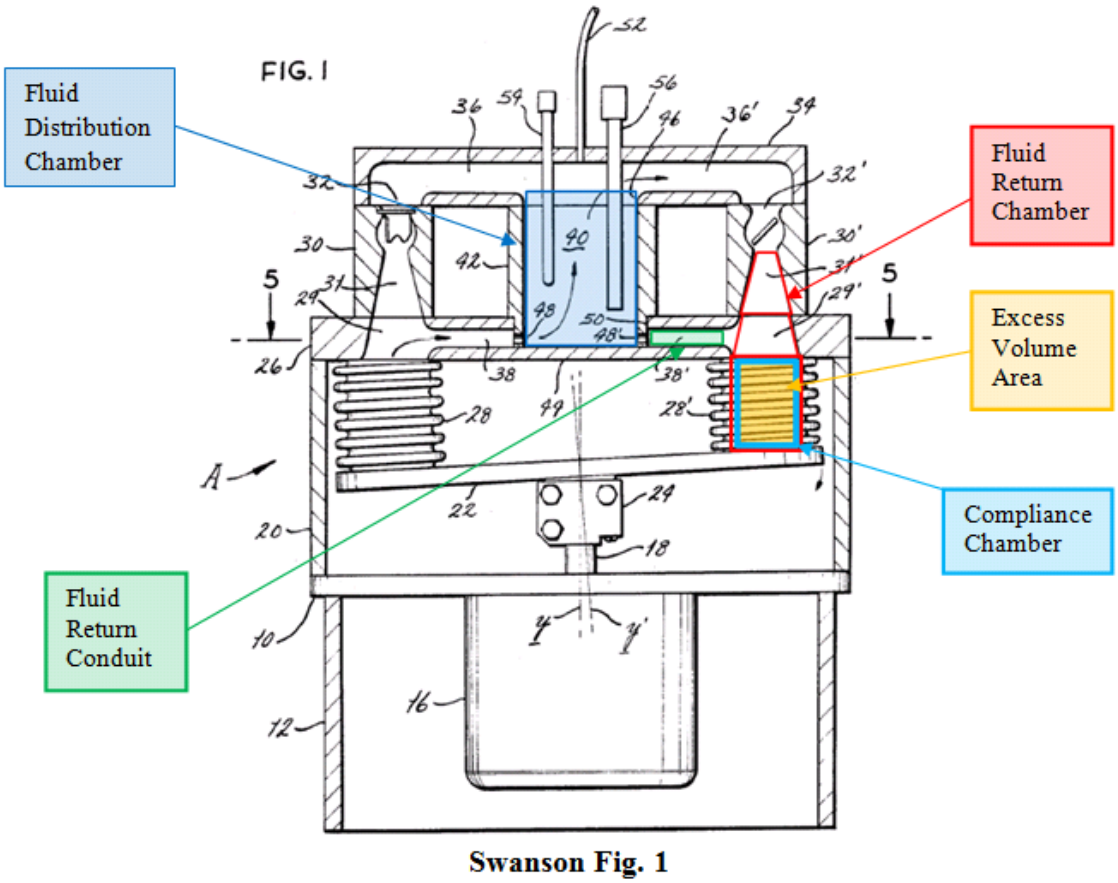
As Professor Billiar explains, System A features a rotating swash plate which repeatedly compresses and expands bellows connected thereto. *See* Billiar Decl. ¶ 66. Figure 1 illustrates that, as a result of rotating the tilted swash plate, when bellows 28' is compressed, bellows 28 is extended. *See id.* According to Professor Billiar, one of skill in the art would understand that, when bellows 28' is extended, bellows 28 is compressed. *See id.* The bottom of the bellows are a pressure source in Swanson's System A. *See id.* As Professor Billiar point out, Swanson describes a "bellows-actuated fluid oscillator for cycling fluid at a frequency of from several hundred to several thousand cycles per minute in a completely closed liquid condition." *See id.*. Thus, Professor Billiar concludes that Swanson's System A features "a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an

accelerated pulsed rate of greater than 200 beats per minute within the device;" as required by the first element of claim 1 of '935 patent. *See id.*

Professor Billiar also explains that Swanson's System A includes a chamber for receiving test samples. *See id.* at ¶ 67. As Professor Billiar point out, Swanson's chamber "provides testing in a completely sealed fluid environment." *See id.* (quoting Swanson 2:4-11). According to Mr. Girard, "[i]n order for [a device] to function as a heart valve testing system, the test chamber must be pressurizable." Girard Decl. at p. 11. Applying Mr. Girard's reasoning to Swanson's heart valve testing system, Professor Billiar concludes that System A's chamber must be pressurizable. *See* Billiar Decl. ¶ 67. Thus, Professor Billiar concludes that Swanson's System A features "a pressurizable test chamber for containing the test system fluid;" as required by the second element of claim 1 of '935 patent. *See id.*

Professor Billiar explains that, as illustrated in Figure 1, System A's fluid test environment includes a fluid distribution chamber (chamber 40), a fluid return chamber (components 31, 29, 28), and fluid return conduits (passage 38). *See* Billiar Decl. ¶ 68. According to Professor Billiar, Swanson's System A operates by compressing a bellows, such as bellows 28, to advance test system fluid through diametrically opposed valves along fluid path indicated by the arrows in Figure 1. *See id.* When bellows 28 contracts, fluid is advanced through fluid distribution chamber (component 40) to a first side of valved prosthetic device (valve 32'). *See id.*. Fluid then passes through valved prosthetic device 32' into the fluid return chamber (components 31', 29', 28') positioned on a second side of the valved prosthetic device. *See id.* Fluid return conduits (passage 38)

structurally and fluidically connect the fluid distribution chamber with the fluid return chambers. *See id*. Professor Billiar's visual aid based on Swanson's Figure 1 is copied below:



Swanson Fig. 1

See Billiar Decl. ¶ 68.

Mr. Girard indicates that when "test fluid is able to move from [a first component] to [a second component], … the two are 'in fluid communication.'" Gerard Decl. at p. 13. Applying Mr. Girard's interpretation of "in fluid communication," without adopting it or considering whether it is appropriate, Professor Billiar finds that System A's fluid distribution chamber (chamber 40) is in fluid communication with the pressure source (bottom of bellows). *See* Billiar Decl. ¶ 69. Thus, Professor Billiar concludes that

Swanson's System A features "a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;" as required by the third element of claim 1 of '935 patent. *See id.*

Applying Mr. Girard's interpretation of "in fluid communication with," Professor Billiar notes that each component in System A's sealed fluid environment is in fluid communication with all of the other components in the environment. *See* Billiar Decl. ¶ 70. For example, the volumes provided by either extending bellows are in fluid communication, as defined by Girard [cite], with their respective fluid return chambers (components 31', 29', 28' in combination). *See id.*

For the reasons explained above, Professor Billiar concludes that Swanson's System A features "a fluid return chamber positioned on a second side of the valved prosthetic device; [and] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber;" as required by the fourth and fifth elements of claim 1 of '935 patent. *See* Billiar Decl. ¶ 71.

Professor Billiar explains that a closed cyclic heart valve testing system must include a volume where the displaced fluid can be received or stored in order to allow test system fluid to be displaced (i.e., flow). *See* Billiar Decl. ¶¶ 38, 72. Professor Billiar notes that the '935 Patent addresses this requirement with a "compliance chamber 135 provid[ing] [an] excess volume area for fluid to move into when the piston 114 performs a compression stroke." *See id.* at ¶ 72 (citing '935 patent 12:4-6). Professor Billiar explains that, in Swanson, the expanded bellows provide an excess volume area for fluid to move into. *See id.* For example, as Swanson's Figure 1 illustrates, expanded bellows

28 provides a volume for storing test system fluid as compare to unexpanded bellows. *See id*. Thus, Professor Billiar concludes that Swanson provides an "an excess volume area … providing a volume for storing a volume of test system fluid" as required by the sixth and final element of claim 1 in the '935 Patent. *See id.*

According to Mr. Girard, if a heart valve testing device "operates at an accelerated rate, … [its] excess volume area is 'capable of operating at the accelerated pulsed rate.'"[10] Gerard Decl. at p. 13. Applying Mr. Girard's interpretation of an "excess volume area capable of operating at the accelerated pulsed rate," without adopting it or considering whether it is appropriate, Professor Billiar finds that Swanson has an excess volume area capable of operating at an accelerated pulsed rate because System A operates at several hundred to several thousand cycles per minute and includes a volume for storing test fluid in expanded bellows. *See* Billiar Decl. ¶ 73. Thus, Professor Billiar concludes that Swanson's System A features "an excess volume area capable of operating at the accelerated pulsed rate," as required by the sixth element of claim 1 of '935 patent. *See id.*

Again applying Mr. Girard's interpretation of "in fluid communication with," Professor Billiar finds that the volume for storing test fluid in expanded bellows is in fluid communication with the fluid return chamber (components 31', 29', 28') because fluid is able to move from that volume to that chamber. *See* Billiar Decl. ¶ 74. Thus, Professor Billiar concludes that Swanson's System A features "an excess volume area …

[10] Mr. Girard's interpretation effectively eliminates the limitation that the Patent Office required BDC to add before allowing the '935 Patent claims.

in fluid communication with the fluid return chamber," as required by the sixth element of claim 1 of '935 patent. *See id.*

According to Professor Billiar, the test fluid in heart valve testers is generally considered incompressible. *See* Billiar Decl. ¶¶ 37, 75. Professor Billiar notes that Swanson discloses "the test fluid may be sterile human blood plasma … or other suitable fluids." *See id.* at ¶ 75 (quoting Swanson 3:12-16). In Professor Billiar's opinion, one of skill in the art would understand "suitable fluids" to be incompressible. *See id*. In Professor Billiar's opinion, one of skill in the art would understand that there is no compression of an incompressible fluid. *See id.*

Nonetheless, Mr. Girard states that, at times, "test system fluid is under compression." Gerard Decl. at p. 13. In Professor Billiar's opinion, Mr. Girard is interpreting "test system fluid … under compression" to mean "test system fluid … under pressure." *See* Billiar Decl. ¶ 76. Applying Mr. Girard's interpretation of "test system fluid … under compression," without adopting it, Professor Billiar concludes that Swanson provides an "excess volume area … providing a volume for storing a volume of a test system fluid when the test system fluid is under compression," as required by the sixth element of claim 1 in the '935 Patent. *See id.*

Mr. Girard says that a "person of ordinary skill would understand the term 'compliance chamber' to mean 'a cavity or volume that functions to absorb some of the pressure in the system.'" Gerard Decl. at p. 14. In support, Mr. Girard cites part of a sentence from a patent related to the '935 patent. But Professor Billiar notes that Mr. Girard does not explain why his proposed definition does not include the second function

in the sentence. *See* Billiar Decl. ¶ 77. Whereas Mr. Girard states that "the specification notes that [the compliance chamber] may *be* air or another gas," it actually states that the compliance chambers 135 may merely "*contain*" air or another gas. *See id.* (citing '538 patent 8:66-9:1) (emphasis added). And the specification also states that "the compliance chambers 135 may house a porous material or an elastomeric material." *See id.* (citing '538 patent 9:4-6). Mr. Girard also does not explain why none of BDC's statements about compliance chambers during prosecution (of the '935 patent and '224 patent) would affect how one of skill in art would understand that term. *See id.*

Having not had sufficient time to reach a conclusion as to the meaning of "compliance chamber" in the proper context, Professor Billiar reserves the right to disagree with Mr. Girard's proposed construction. *See* Billiar Decl. ¶ 78. Nonetheless, applying Mr. Girard's interpretation of "compliance chamber," without adopting it or concluding that it is appropriate, Professor Billiar finds that Swanson's bellows are a compliance chamber. *See id.* Professor Billiar explains that, when Swanson's bellows expand and store test system fluid, they absorb some of the pressure in the system. *See id.* Indeed, if a first bellows did not expand and store some of the test fluid when a second bellows compressed, Swanson's System A would not be able to function, and the pressure within the system would become infinite. *See id.*

Without addressing how BDC's statements about compliance chambers during prosecution would affect how one of skill in art would understand the term, like Mr. Girard, Professor Billiar notes that one of ordinary skill in the art would understand a meaning of compliance to be a change in volume corresponding to a change in pressure.

See Billiar Decl. ¶ 79. Swanson's bellows expand and contract in response to changes in pressure. *See id*. Thus, Professor Billiar finds that, applying the foregoing meaning, one of skill in the art would consider Swanson's bellows, or a portion thereof, to be compliance chambers. *See id*. Again, Swanson's System A includes a fluid return chamber (components 31', 29', 28') and the bellows is within that chamber. Thus, Professor Billiar concludes that Swanson's System A features an "excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber," as required by claim 9 of '935 patent. *See id.*

In Professor Billiar's opinion, the Patent Office would not have concluded that an excess volume area "capable of operating at the accelerated pulsed rate" distinguished over the prior art if it had known that BDC would apply Mr. Girard's interpretation of that limitation. *See* Billiar Decl. ¶ 80. That is, according to Professor Billiar, the Patent Office would not have allowed the claims if it understood BDC's position that any tester including an excess volume area and capable of operating at the accelerated pulsed rate would meet the limitation. *See id.*

Finally, Professor Billiar concludes that, because it discloses a system that includes every element of claims 1 and 9 of the '935 patent, Swanson anticipates claims 1 and 9 of the '935 patent. *See* Billiar Decl. ¶ 81.

5. BDC's Claims of Infringement of the '224 Patent Fail as a Matter of Law

As explained above, BDC failed to properly construe the terms of the asserted claims of the '224 Patent. *See supra* Section III.B.3. Accordingly, BDC has not met its

burden of establishing a likelihood of success on the merits of its claims of infringement of the '224 Patent. *See, e.g.*, *Fair Isaac*, 2006 WL 1283852 at *7.

6. The '224 Patent is Invalid for Lack of Written Description and for Anticipation or Obviousness Over Pickard

During the prosecution of the '224 patent, the Patent Office concluded that U.S. Patent No. 4,682,491 to Pickard ("Pickard") "teaches a method for operating an accelerated cyclic test system for evaluating a valved prosthetic device … comprising storing volume of test system fluid in an excess volume area … [;] and releasing the stored volume of test system fluid during a return stroke that closes the valved prosthetic device … ." Ex. 3 at 31 (March 20, 2015 Non-Final Rejection). In other words, the Patent Office concluded that Pickard disclosed the method of claim 1 as it was originally presented to the Patent Office. *See* Billiar Decl. ¶ 40. Except with respect to the word "accelerated" in the preamble, BDC did not challenge the Patent Office's conclusions. *See id.* And Professor Billiar agrees with the Patent Office's conclusion that Pickard disclosed the method of claim 1 as it was originally presented to the Patent Office. *See id.*

During the prosecution of the '224 patent, the Patent Office also concluded that "Pickard teaches compressing a volume of compressible gas with the volume of test system fluid to provide a spring force counter to and in response to a pressure on the test system fluid when the volume of test system fluid is stored in the excess volume area." Ex. 3 at 31 (March 20, 2015 Non-Final Rejection). In other words, the Patent Office concluded that Pickard disclosed the limitations of claim 6. *See* Billiar Decl. ¶ 41.

Professor Billiar agrees with the Patent Office's conclusion that Pickard teaches the limitations recited in claim 6 of the '224 patent. *See id.*

The Patent Office rejected claim 1 and claim 6 for anticipation by Pickard. *See* Ex. 3 at 31 (March 20, 2015 Non-Final Rejection). Although it tried, BDC was unable to convince the Patent Office that the inclusion of the word "accelerated" in the preamble of rejected claim 1 distinguished Pickard. *See id.* at 32 (May 14, 2015 Applicant-Initiated Interview Summary).

To overcome the rejection in view of Pickard, BDC amended claim 1 to include new language. BDC amended claim 1 to require "driving a test system fluid … at an accelerated pulsed rate of greater than 200 beats per minute." *Id.* at 11 (June 17, 2015 Response). Before BDC amended claim 1 to require greater than 200 beats per minute, the '224 application did not disclose any particular number of beats per minute for testing. *See* Billiar Decl. ¶ 44. In other words, the '224 application did not disclose the invention BDC now claims. Accordingly, the '224 patent is invalid for lack of written description. *See Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328 (Fed. Cir. 2000) (affirming invalidity for lack of written description after claim amended to recite a numerical ratio, but "nothing in the written description . . . would suggest to one skilled in the art that the . . . ratio is an important defining quality.").

BDC argued that its new claim language distinguished Pickard. *See* Ex. 3 at 14-18 (June 17, 2015 Response). And based on BDC's amendment and its argument, the Patent Office allowed the claims of the '224 patent. *See* Billiar Decl. ¶ 45. The Patent Office stated that it allowed the claims because Pickard failed to specifically teach "an

accelerated cyclic test system for evaluating a valved prosthetic device with a pulsed rate of greater than 200 beats per minute in independent claim 1 when combined with the limitations of an excess volume area (which is a term of art …) and its location ….” Ex. 3 at 7 (September 17, 2015 Notice of Allowance).

There are several problems with the Patent Office’s statement of reasons for allowance. For example, the Patent Office identified “excess volume area” as a term of art—without explaining what it understood that term to mean. *Id*. Moreover, the Patent Office cited the location of the excess volume area, but there is no such location recited in the method of claim 1. In other words, the Patent Office clearly relied on BDC’s argument as its reason for allowing the ‘224 patent claims. *See* Billiar Decl. ¶ 45. Setting aside the excess volume area (which the Patent Office had previously found in Pickard) and it unrecited location—the Patent Office appears to have allowed the claims based on the new rate of greater than 200 beats per minute.

Again, no particular number of beats per minute appeared in the ‘224 application. So where did “greater than 200 beats per minute” come from? In its response, BDC included Table 1 of ISO 5840. Ex. 3 at 16 (June 17, 2015 Response). According to Table 1 of ISO 5840, a heart valve substitute operational environment includes a heart rate up to 200 beats per minute. *See* Billiar Decl. ¶ 48. BDC used that information in ISO 5840 to persuade the Patent Office that “accelerated” means at greater than 200 beats per minute. *See id.* But contrary to BDC’s suggestion, ISO 5840 does not define “accelerated” testing as testing at greater than 200 beats per minute. *See id.* at ¶ 47.

BDC then suggested that Pickard discloses a "real time" system, and that a "real time" system would have been operated at fewer beats per minute than its method. *See* Ex. 3 at 14-18 (June 17, 2015 Response); Billiar Decl. ¶ 46. In fact, like the '224 application, Pickard did not disclose any particular number of beats per minute for testing. *See* Billiar Decl. ¶ 49.

BDC also suggested that compliance chambers had not been used in heart valve accelerated durability testers. *See* Ex. 3 at 17-18 (March 20, 2015 Non-Final Rejection). But the 2005 edition of ISO 5840 suggested the use of a compliance chamber in heart valve durability testing. *See* Ex. 7 at Annex F (ISO 5840); Billiar Decl. ¶ 54. And heart valve accelerated durability testers were known to use compliance. *See, e.g.*, Ex. 12 at 153 (Reul); Ex. 11 at 186 (Iwasaki); Billiar Decl. ¶ 54. Indeed, commercial heart valve accelerated durability testers were known to use compliance. *See* Ex. B at 186 (Lu).

Riffing on the new beats per minutes requirement, BDC argued that Pickard's system compliance served a different purpose than the excess volume area of the '224 patent claims. Ex. 3 at 14 (June 17, 2015 Response). But Picard's compliance element involved "compressing … compressible gas" as in claim 6 of the '224 patent. *See* Billiar Decl. ¶ 53. According to Professor Billiar, the function of Picard's compliance element and claim 6's "compressing … compressible gas" are the same action, and have the same effect. *See* Billiar Decl. ¶ 53.

In Professor Billiar's opinion, the Patent Office may not have allowed the '224 patent if it had been provided all of the relevant information in ISO 5840, such as ISO 5840's recommendation of the use of compliance chambers in accelerated heart valve

durability testing. *See* Billiar Decl. ¶ 55. In Professor Billiar's further opinion, the Patent Office may not have allowed the '224 patent if it had told that compliance had been used in accelerated testing of prosthetic heart valves. *See id.* at ¶ 56.

What is more, the Patent Office did not consider U.S. Patent No. 3,208,448 to Woodward during prosecution of the '224 patent. *See* Billiar Decl. ¶ 50. Woodward teaches about an artificial heart pump circulation system. *See id.* at ¶ 50. Woodward teaches that it was known in the art that a normal physiological heart rate for a normal young adult includes a range of from 60 bpm (resting) to 160-180 bpm (heavy exercise) to 240-270 bpm (short exhaustive work). *See* Ex. 9 at 13:38-49 (Woodward). Professor Billiard explains that, in other words, Woodward discloses that a normal physiological range can go up 270 bpm. *See* Billiar Decl. ¶ 50.

Pickard teaches that an "object of the present invention to provide a method and apparatus for testing of a prosthetic heart valve under individualized test conditions simulating a specific human circulatory environment into which the valve may be placed." Ex. 9 at 2:57-61 (Pickard). According to Professor Billiar, one of skill in the art would have been motivated by Woodward to configure Pickard's system and use Pickard's method to test heart valves at greater than 200 bpm to simulate the 240-270 bpm of a normal young adult during short exhaustive work. *See* Billiar Decl. ¶ 51.

In Professor Billiar's opinion, the Patent Office would not have accepted a "rate … greater than 200 beats per minute" as a distinguishing limitation if it had understood that Pickard's goal of simulating a specific human circulatory environment would include

testing at rates above 200 bpm, in accordance with Woodward's disclosure that normal rates include 240-270 bpm. *See* Billiar Decl. ¶ 57.

In Professor Billiar's opinion, it would not have challenged one of ordinary skill in the art before 2009 to operate Pickard's test system at 240-270 bpm given the minimum frequency range including 200 bpm in ISO 5840, and one of ordinary skill in the art would have had a reasonable expectation that Pickard's method would work at such a rate. *See* Billiar Decl. ¶ 52. Professor Billiar also notes that, at the relevant time, one of ordinary skill in the art would have reasonably expected be successful using Pickard's methods at up to the 270 bpm, disclosed in Woodward. *See id.* In other words, Professor Billiar concludes that claims 1 and 6 of the '224 patent are obvious over Pickard in view of Woodward's disclosure of a normal heart rate greater than 200 bpm. *See id.* at ¶ 58.

C. The Balance of the Hardships Weigh Strongly Against a Preliminary Injunction

Any alleged harm to BDC in the absence of a preliminary injunction is far outweighed by the harm to TA Instruments if it is shut out the U.S. market or forced to redesign its heart valve tester. *See, e.g.*, *Rudolph Techs., Inc. v. Camtek Ltd.*, No. 15-1246, 2015 WL 5039295, at *16 (D. Minn. Aug. 26, 2015) ("While Rudolph will undoubtedly suffer harm if forced to compete against a similar, perhaps infringing, product ... the harm Camtek will incur if completely shut out from the United States market is a greater potential harm."). Indeed, even Dr. Weinberg states that customers prefer to buy a single model of test instrument for consistency within their test protocol. *See* Weinberg Decl. ¶ 12. TA Instruments' "reputation and customer relationships" will

be damaged if the DuraPulse HVT is forced off the market. *See Binney & Smith v. Rose Art Indus.*, Inc., No. 94-6882, 1995 WL 103532, at *15 (N.D. Ill. Mar. 3, 1995).

BDC's only balance of the harms argument is by reference to its irreparable harm argument. As discussed above, these alleged harms may be addressed by a damages award. *See supra* Section III.A.6. By contrast, the hardship to TA Instruments significantly outweighs the hardship to BDC, and potentially includes losses that are themselves difficult to quantify and could extend far from the accused heart valve test device. Accordingly, this factor favors not entering an injunction.

D. A Preliminary Injunction is Contrary to the Public Interest

A preliminary injunction here is contrary to the public interest. Heart valve testing is necessary to get life-saving prosthetic heart valves onto the market. *See* Nickel Decl. ¶ 2. An injunction would prevent heart valve manufacturers access to the well-established TA Instruments line. "[F]or good reason, courts have refused to permanently enjoin activities that would injure the public health." *Cordis Corp. v. Boston Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004). Courts have recognized that promoting availability of medical devices is in the public interest. *See id.* ("[A] strong public interest supports a broad choice of drug-eluting stents."); *see also Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 561 (D. Del. 2008) (same); *see also Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 864 (Fed. Cir. 1987) (permitting party to continue manufacture of pacemaker leads was in the public interest); *Hologic, Inc. v. Senorx, Inc.*, No. 08-00133, 2008 WL 1860035, at *19 (N.D. Cal. Apr. 25, 2008) ("[T]there is a public interest in expanding ... treatment possibilities.") A preliminary

injunction preventing heart valve manufacturers and researchers access to TA Instruments' systems is contrary to the public interest.

BDC's public interest argument relies entirely on the general value of the patent system. BPI at 29. But, "although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988). This is a case in which the specific public interest in support research into medical devices weighs against entry of a preliminary injunction.

E. If a Preliminary Injunction Were Entered, BDC Should Pay a Substantial Bond

If a preliminary injunction were warranted in this case—which it is not—BDC should have to pay a substantial bond.

As explained above (*see supra* Section III.C), if a preliminary injunction were entered, TA Instruments would not only lose significant sales while the injunction is in effect, but would suffer substantial injury to its reputation and good will, resulting in lost sales of other testing instruments. An injunction bond must "pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65. BDC's proposal that the bond be a mere $10,000—a tenth of the list price of *one* TA Instruments' device—is unsupportable. In light of the substantial costs associated with TA Instruments' loss of sales during an injunction, and irreparable harm

to its reputation and good will, were a preliminary injunction to be entered, the bond should be at least $1,000,000.

IV. CONCLUSION

Because BDC fails to establish any of the criteria necessary for entry of a preliminary injunction, as explained above, its motion should be denied.

Dated: December 22, 2017

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